

EVALUATING THE EFFECT OF PATTERN OF INFLATION AND DEFLATION AND
CYCLE TIME ON THE PRESSURE RELIEVING CHARACTERISTIC OF A DYNAMIC
SEAT CUSHION USING SEAT INTERFACE PRESSURE MEASUREMENTS

By

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Abstract

Ulceration due to pressure can occur in any individual who is restricted to a prolonged stay in a bed or a chair with no pressure relief. Intermittent pressure relief has been recommended as a means to lower the risk of pressure ulcer development. Active cushions cyclically change the area of exposure to pressure. The design parameters of these cushions have been rarely discussed and studied.

The main objective of our study was to examine the effect of pattern of inflation/deflation and cycle time on pressure relieving characteristics of active cushions and to compare the performance of these active cushions with a passive cushion. Two custom active cushions were developed based on Roho Quadtro passive cushion design with inflation/deflation patterns: checkerboard (CHK) and column (COL). These were compared to a passive Roho Quadtro cushion (PAS). Two cycle times, 6min. and 12min., of inflation/deflations were tested. Ten non-disabled individuals were tested. Interface pressure was measured for 24min. using the Xsensor pressure mapping system. Peak and mean pressures, percent surface area in contact under 30 mmHg for a cumulative time of at least 5 minutes ($S>5$), mean percentage of activated sensors under three thresholds (20, 30 and 40 mmHg; $P<20$, $P<30$ and $P<40$ respectively) were calculated.

Results indicated that COL had the best pressure relieving characteristics. COL had significantly higher $S>5$, $P<20$ and $P<30$ compared to both CHK and PAS, while CHK had significantly higher $S>5$ and $P<20$ compared to PAS. Cycle time of 12min. developed higher peak pressures compared to 6min. cycle. It was clear that active cushions have an advantage over passive. The design of these custom cushions: air channel distribution and pattern of connection, may have

influenced the results. Further testing with disabled individuals and re-designed cushions is needed to fully understand the importance of pattern, cycle time and air cell size.

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Motivation

Wheelchair users everywhere face many challenges in their life, mobility and access to name a few. Potentially the most devastating of them all is a pressure ulcer. Painful and debilitating, pressure ulcers are a major cause of discomfort to both the patient and their caregiver. They impose a heavy burden on the healthcare system and significantly lower the quality of life experienced by the individual. Treating pressure ulcers can cost anywhere from \$15,000.00 to \$60,000.00 and in most cases require a lengthy stay at the hospital. The individual, in cases of severe ulceration, may end up undergoing surgical interventions including debridement of the affected wound and bone removal.

Ulceration due to pressure can occur in any individual who is restricted to a prolonged stay in a bed or a chair with no pressure relief. Although a large number of factors in addition to pressure can increase the likelihood and severity of the ulceration, contact pressure stands out as one of the major influencing parameters. The problem is compounded in a wheelchair bound individual, since only a small area of the body has to support a large part of the body mass. Conceivably, a majority of people suffering from pressure ulcers are non-ambulant wheelchair bound. An estimated 30% of the paraplegic population and 50% of all quadraplegics will require hospitalization because of pressure related problems during their lifetime. The prevalence of pressure ulcers is even higher in geriatric population. Most find the condition affecting them emotionally, mentally and socially. With the number of individuals using wheelchairs increasing every year, it has become imperative that an effective method of preventing pressure ulcers be found and experimentally ascertained to be effective.

As can be inferred prevention is the best way of combating pressure ulceration, but lack of objective data on methods and their effectiveness make it quite difficult to distinguish between

techniques. Pressure relief maneuvers, in most cases, are still performed by care takers of the individual by physically changing their position. Individuals who have the requisite upper body strength relieve pressure through a regime of exercises.

Using cushion based relief technology isn't new. Kosiak et al in 1961 recommended the use of alternating pressure as it "...is impossible to completely eliminate all pressure for a long period of time". In the time since, there have been many attempts at creating a cushion that alternates pressure effectively, but even today researchers are still debating the value of dynamic cushions.

In the following work, we explored the efficacy of dynamic seat cushions, with healthy subjects. A novel alternating pressure seat cushion was used to determine optimal cycle time and pattern for alternation with respect to interface pressure.

It is hoped that this knowledge will benefit the research community and help us move a step closer to safeguarding the health and personal freedom of individuals at risk for pressure ulcers.

Chapter 1 Introduction

1.1 Pressure Sores

A localized necrosis of skin tissue due to prolonged application of pressure or shear forces and/or friction is called a pressure sore (1,2). As a pressure sore develops, the necrosis deepens and penetrates to deeper tissues. More recently the theory of deep tissue injury (DTI) has been gaining wide spread acceptance. It is now believed that there exists another pathway to pressure sores and that is through damage to deep tissue near bony prominences due to pressure applied externally. In either of these cases, the situation is often complicated by concomitant conditions (sepsis, infection etc) which can be life-threatening (3). Pressure sores are a reality that many wheelchair users live with. It is estimated that nearly 30% of the paraplegic population and 50% of all quadraplegics will require hospitalization because of pressure related problems during their lifetime (4). Spinal cord injured individuals make up a significant portion of the wheelchair bound individuals. Owing to the scale of this group, many prevalence and incidence studies have focused on this one group.

Pressure sores impose a heavy burden on the health care system, through financial expenditure by using up the limited labor resources available (5). Treating pressure sores can be expensive, costing anywhere from \$15,000 to \$60,000 and is often accompanied by lengthy hospitalization (6-8). The cost increases with the level or grade of pressure ulcer. Recently, an estimated average of \$124,327 per case was spent on treating community acquired level IV pressure sores (9). In addition to the financial burden, individuals suffering from pressure sores experience deteriorating quality of life. It taxes an already physically impaired individual and further reduces independence and lowers their self-esteem and self-worth (10,11). The condition not only affects the sufferer but also his/her care-givers and family.

Of the many risk factors, individuals confined to a bed or chair are at a higher risk of developing pressure sores (12). Relatively little information is available on prevalence of pressure sores in wheelchair bound individuals but there is an overall impression that it is higher. The few studies that report prevalence have figures that range from 24% (13) to 60% (14), with higher prevalence in the geriatric population (15,16). Pressure sores mainly occur under bony prominences, with the sacrum, coccyx and ischial tuberosities being the most common sites, for both single- and multiple-ulcers (17,18). Sores near the ischial tuberosities account for 63% of all recurring sores in SCI individuals (19).

There is a high probability of recurrence of pressure sores even if an earlier sore heals (20). The healing itself takes a long time and requires quite an effort from both the care-givers and the individual suffering from sores. Although some studies have reported 50%-70% of pressure sores healing through nonsurgical interventions (21), the price paid by the individual both in terms of dollars and human suffering necessitates the improvement of prevention measures. Incidence of pressure sores can be significantly lowered (by as much as 50%) through preventive measures (22-24).

There are many preventive methods available which depend on the level of the individual's physical impairment: from repositioning every few minutes by the individual themselves or with the help of a care-giver, to the use of specialized support surfaces. However, none so far has provided complete protection from pressure sore incidence (25-29). Pressure sores are still widespread and researchers the world over are working on methods and devices that may lower their incidence. With an ever growing geriatric and mobility impaired population it is fair to expect the problem will only keep growing.

1.1.1 Nomenclature and Classification

Pressure sores are also known by a number of other terms: pressure ulcers, decubitus ulcers, bed sores and ischemic ulcers. The most commonly used term is decubitus which in Latin "decumbere" means "to lie down"(30), since it was earlier believed to have resulted through prolonged recumbency. It is now thought to occur from prolonged application of pressure in any direction on skin tissue and hence "pressure sores" or "pressure ulcers" seems to be the most appropriate term to use.

One of the first steps in studying and comparing pressure sore epidemiologic data is classifying them. Several systems exist for classifying pressure sores and each has its share of advantages and disadvantages (15). The National Pressure Ulcer Advisory Panel (NPUAP 1989) devised a classification system that arranged pressures sores into four stages depending on the severity of ulceration (Figure 1.1). In 2007, the system was updated with addition of two stages on deep tissue injury (Figure 1.2). The following is the updated staging system:

Suspected Deep Tissue Injury:

An underlying soft tissue damage from pressure and/or shear that causes visible skin tissue to change color or develop blood-filled blisters. It is quite difficult to assess DTI in dark skin tones, and may remain undetected until the individual feels pain or extreme discomfort.

Stage I:

Considered a "heralding sign of risk", Stage 1 includes localized non-blanchable redness of intact skin usually over a bony prominence. Like suspected deep tissue injury, detecting this stage in individuals with dark skin tone is quite difficult.

Stage II:

Is a shallow open ulcer that may present itself as a blister or a crater. This stage involves partial thickness loss of dermis or epidermis. There is no slough present and the ulcer is dry.

Stage III:

Is full thickness tissue loss (open wound). It includes subcutaneous tissue and may have visible subcutaneous fat. Bone/tendon is not visible or directly palpable.

Stage IV:

Is Full thickness tissue loss with the involvement of bone, tendon or muscle. It also includes undermining and tunneling.

Unstageable:

Full thickness tissue loss with base of the ulcer covered with slough and/or eschar in the wound bed.

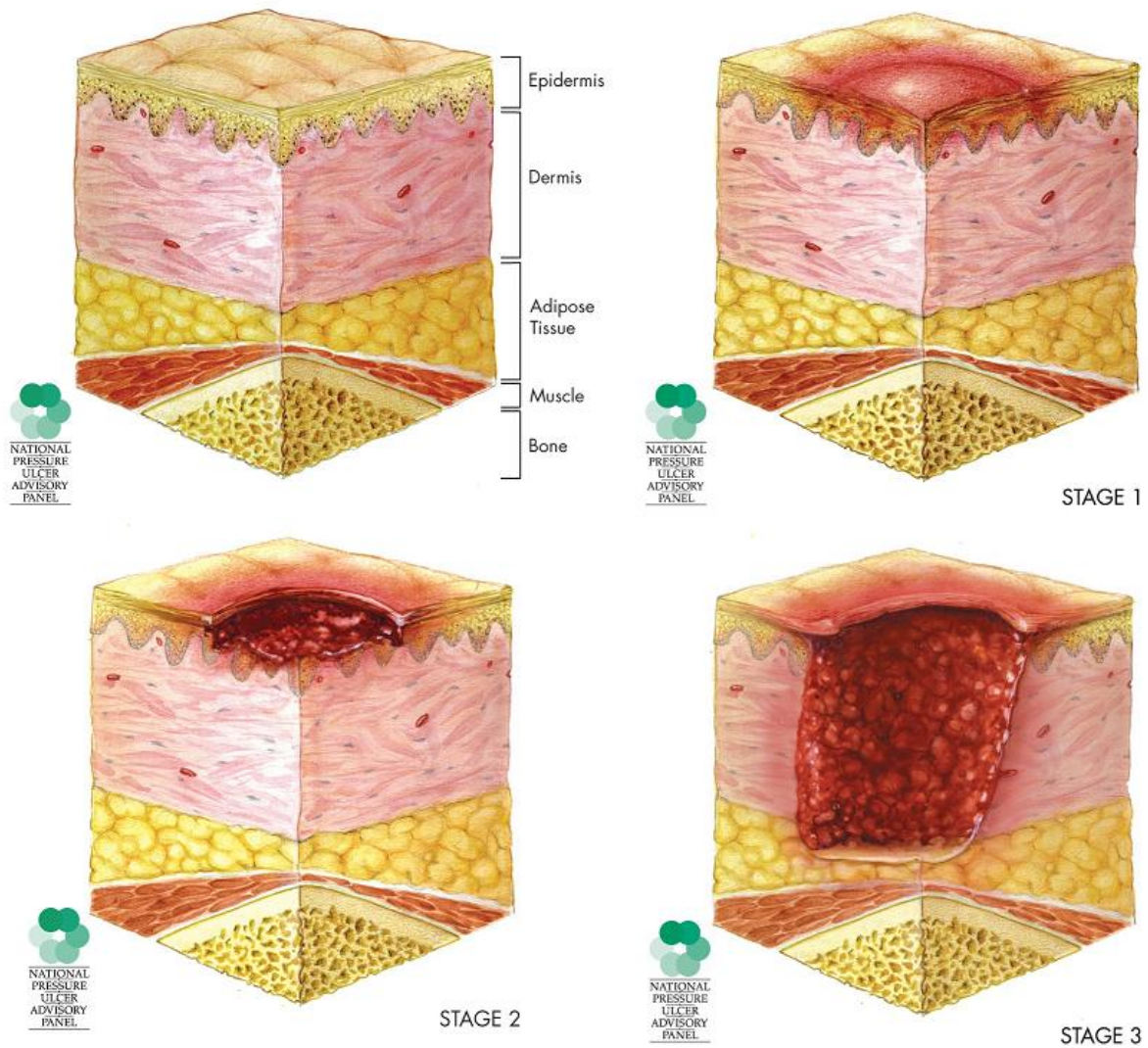


Figure 1.1 (Reprinted with permission) Normal, Stage 1, Stage 2 and Stage 3 pressure ulcer illustrations are shown.

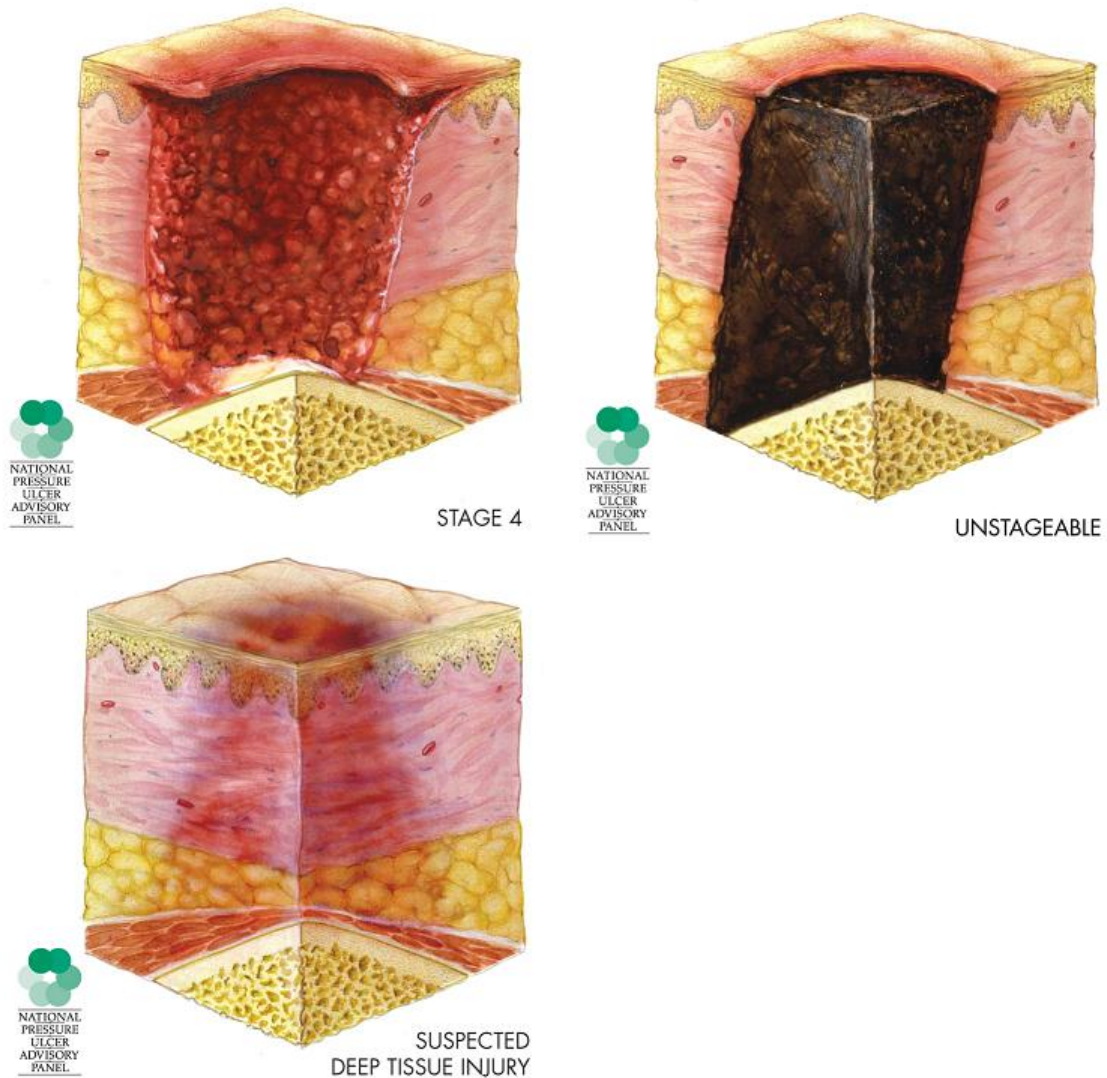


Figure 1.2 (Reprinted with permission) Stage 4, Unstageable pressure ulcers and deep tissue injury are shown.

Care must be taken to carefully debride or clear any wound before full assessment. DTI may be difficult to assess in individuals with lack of sensation of pain, and in most of these cases it is often not detectable until it reaches an advanced stage, making it difficult to treat.

1.1.2 Pathophysiology

The above mentioned classification/stages closely follow the actual pathophysiology of pressure sores. Most stages have been well investigated; however, much confusion still prevails in describing DTI and its pathology.

We can categorize pressure sore pathophysiology as Surface Pressure Ulcers (SPU) and Deep Pressure Ulcers owing to Deep Tissue Injury (DTI). SPU's are caused by skin damage due to inadequate capillary blood flow resulting from unrelieved external pressure, shearing/frictional forces and/or many other concomitant factors including poor nutrition and diabetes. If these sores remain untreated, they extend to deeper tissue. DTI is believed to originate in deeper subcutaneous tissue, especially near bony prominences (31). DTI can be fatal as by the time it is detected, substantial tissue damage has often already occurred. Tissue damaged due to DTI usually takes longer time to heal and requires normal or higher levels of blood perfusion. Most individuals who suffer DTI have other pathologies which make reinnervation and revascularization difficult. This makes DTIs even more devastating for the individual.

1.1.2.1 - Surface Pressure Ulcers:

Pressure ulcers until recently were thought to originate only on the surface and travel deeper in the absence of treatment. There have been a few explanations for this phenomenon, and the most commonly hypothesized are: ischemia resulting from vascular occlusion (32-35); injury caused by reperfusion associated with inflammatory response (36-38); mechanical deformation of tissue cells over a period of time (39,40); accumulation of metabolic waste products and enzymes etc. owing to impaired lymphatic drainage (4,40-43).

The following is additional explanation of path followed by a pressure ulcer: As pressure is applied on the skin tissue, there is a temporary paleness observed in the location of the pressure. This is akin to a reddened area of the skin (termed erythema) temporarily turning white when pressure is applied with a fingertip (blanchable). The source of this paleness is vascular and there are no abnormalities observed in the epidermis, pilosebaceous structures and reticular dermis (15).

If pressure is not relieved, the next stage of pressure ulceration begins with blood hemorrhage and platelet thrombi mainly in the papillary dermis with excess blood cells collecting in capillaries and venules, resulting in non-blanchable erythema (15). Although the epidermis still shows no signs of any abnormality, the pilosebaceous structures and subcutaneous fat are often seen to devolve. The body's inflammatory response then kicks in, engorging the epidermal region with esinophils (white blood cells). Crusts and erosions can form and necrosis with or without subepidermal separation is seen. The epidermis may appear atrophic and necrosis of hair follicles may occur.

In time, again with unrelieved pressure, the epidermis starts deteriorating. There is acute inflammation of the papillary and reticular dermis. With the loss of epidermis the dermal papillae becomes visible. Later chronic ulcers show a pattern of diffusely fibrotic dermis followed by complete destruction of cellular detail. However the dermal architecture is preserved (15). Such histopathologic changes demonstrate that pressure ulcer may begin deeper than was initially thought, and that all pressure ulcers may be a result of deep tissue injury (44).

1.1.2.2 - Deep Tissue Injury:

As has been lightly discussed above, surface pressure ulcerations may only be small part of a bigger picture - as deep tissue injury also plays a major role. DTI poses new challenges to researchers, partly because of the nature of the injury, being buried under deep tissue, and because of unavailability of suitable technology which would help study the injury in a more natural setting.

Deep pressure ulcer is a consequence of deep tissue injury which results from compression of tissue, usually between a bony prominence and an external surface (32,33,38,40,44-46).

Ischemia, a well known cause of pressure ulcer, can damage muscle more readily than fat or skin tissue (32,38,46); and this damage can begin as early as within 4 hours of application of pressure (47-49). Deterioration of tissue at such a fast rate yields extensive ulceration and makes deep pressure ulcers potentially even more harmful (50).

Ulceration, which begins at the bone-tissue interface, progresses towards the surface. By the time this ulceration reaches the surface, it leaves behind a necrotic mass of muscle, fascia and other subcutaneous tissue. It has been suggested that the most severe pressure sores are a result of such initial pathological changes and that surface pressure ulcers may indeed be an associated phenomenon (15,39,44). However, a lot more work needs to be done before an early detection method can be developed and clinically deployed.

In recent years, researchers have used the computer modeling approach to study deep pressure ulceration (51-55). Although this approach provides useful insights about the direct consequence of unrelieved pressure it does not fully explain the pathological changes occurring in deep tissue which results in pressure ulcers. There are other research groups which have used currently available imaging technology and/or in vivo animal models to determine the underlying mechanisms that lead to DTI (39,40,45).

There are many theories proposed for onset of pressure ulceration. The most commonly mentioned and well studied is ischemia and impaired lymphatic drainage. Although, this theory can be aptly used in the context of deep pressure ulceration since muscle tissue has deeper vasculature and is sensitive to ischemia, it has not been fully verified and it does not completely explain the onset of tissue damage. Another potential DTI pathway: Ischemia-Reperfusion injury theory states that it is the restoration of blood flow after pressure is relieved, rather than the

ischemia caused by this applied pressure, that causes more damage to the tissue (37). This theory has been extensively used to describe other post-ischemic pathologies, and has only recently been studied in the context of pressure ulceration (37,56). One thing to note about this theory is that the studies that have been done were performed with ischemia-reperfusion cycle times of more than a few hours (37,38). It is not clear yet how the reperfusion over shorter ischemic times affects ulceration.

Mechanical cell damage caused by compression and/or shear has also been suggested as a cause for DTI (40,57,58). It is difficult to assess the effects of mechanical damage due to compression/shear force as ischemia is usually induced by the same force. A hierarchical research approach is suggested when examining the effects of mechanical stress on cell viability (39,40). It has been hypothesized that sustained cell deformation causes cellular damage. This cell damage is believed to cause a ripple effect of volume changes and cytoskeletal reorganization (59,60).

Stekelenburg et al studied both individual and combined effects of mechanical deformation and ischemia in a rat model (61). They applied loads on the hind limbs of rats for a duration of 2 h. Magnetic Resonance imaging was used to determine ischemic loading and further examination was performed through histology. The study concluded that ischemia alone resulted in minor damage that was reversible, while the combined effect of ischemia and mechanical deformation was far more damaging and irreversible. Also, areas of highest strain correlated well with damaged tissue. One can infer that the onset of DTI is caused by prolonged mechanical deformation of tissue and is compounded by ischemia as time progresses.

In the end, all the factors mentioned above may act in varying degrees to ultimately form deep tissue injury and continue/sustain its progression. Regardless, it will be beneficial to lower externally acting forces that may cause deformation and ischemia and to maximize the frequency and length of time for reperfusion.

1.1.3 Etiology

Traditionally, pressure, shear forces, friction and humidity/moisture have been considered as the four major etiological factors for the formation of pressure sores (62-65). Although there are many other factors that do play a role in pressure sore formation, the above four have been routinely hypothesized to be common causative factors in pressure ulceration in a majority of population. Considering the long history of pressure ulcer research, it comes as a surprise that even today researchers are unable to form a clear consensus on pressure sore etiology; with a plethora of theories both supporting and critiquing most, if not all, the suggested etiologies.

1.1.3.1 - Pressure

In the year 1930, Landis determined the mean capillary blood pressure to be around 32 mmHg through micro-injection studies on human subjects (66). Landis was also involved in a later study which showed that the external pressure needed to occlude capillary blood flow to a level below normal flow was in the region of 35-40 mmHg. The results of a similar study (67) correlated well with the Landis' study and suggests similar range of 30-35 mmHg of external pressure needed to lower capillary blood flow.

An assumption made in literature related to pressure ulcers is that higher interface pressure results in pressure ulceration of tissue. And most agree this threshold pressure to be

approximately 35 mmHg. However, the time span of applied pressure may actively increase or decrease the interface pressure required to initiate pressure sores.

Pressure applied externally can be uniaxial, biaxial or triaxial. True triaxial pressure is least likely to cause pressure sores (68). Triaxial pressure is seldom experienced in the daily routine of a wheelchair bound individual. Triaxial pressure is experienced when there is approximately equal force acting from every direction (69). Biaxial pressure can be experienced by the use of a pressure cuff wrapped around a limb. Most pressure ulcers are attributed to prolonged unrelieved uniaxial or point pressure (17,32,68). Point pressure acts between a bony prominence and a hard external surface and is commonly detected over bony prominences of individuals who are chair or bed bound.

An inverse time-pressure curve has been suggested in pressure sore development due to pressure, with rapid ulceration at high pressure and slow ulcer formation at low pressure (32,33,68,70).

Kosiak et al showed that a constant pressure as little as 60 mmHg exerted over a period of only one hour produced noticeable microscopic pathologic changes in dogs (33). The prolonged pressure induced edema, cellular infiltration and extravasation. Husain et al, detected changes in the skin of rats under an unrelieved pressure of 100 mmHg over a period of two hours (46). This agrees with a later work done by Kosiak et al (17). If, however, the same pressure value is applied and intermittently relieved minimal changes were noticed (17,35).

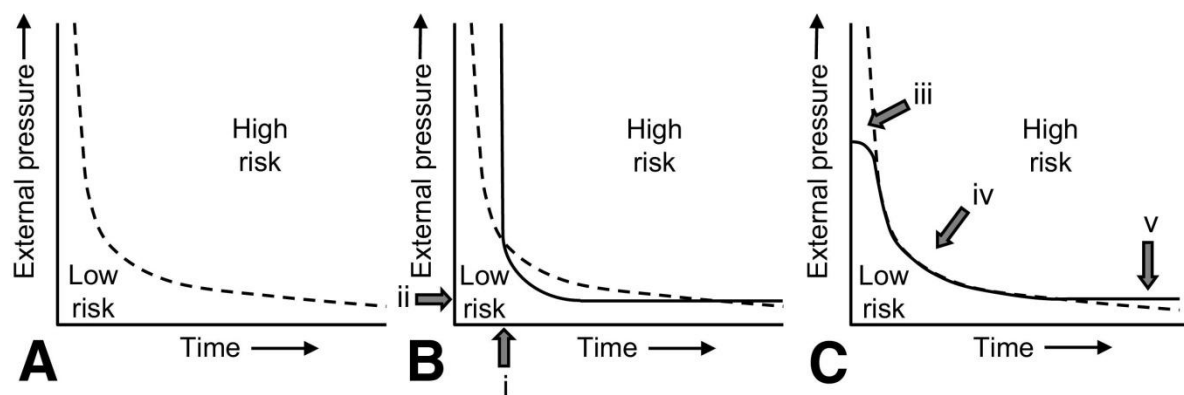


Figure 1.3 (Reprinted with permission) A-Form suggested by Reswick and Rogers(70). B and C - Modifications suggested by Stekelenberg (56)

Stekelenberg et al (56), suggests modification to the form based on Reswick and Rogers original curve. These modifications, as can be seen in Figure 1.3, limit the infinitely high pressure suggested by Reswick and Rogers's original form (70) at low time periods and flattens the lower threshold. Stekelenberg et al hypothesize that there is a limit to the pressure tissue can withstand before undergoing mechanical deformation and ultimately suffering death. They also suggest that at a lower pressure threshold no deep tissue damage can occur. Unless an individual is left with no means of repositioning over very long period it may be difficult to reach the amount of time needed to cause pressure ulcer at lower pressures.

A clinical study on one thousand spinal injury patients over three years revealed that pressures up to - 40 mmHg over the ischial tuberosities, 60 mmHg over the posterior trochanters and 10 mmHg over the junction of the coccyx and sacrum, were usually safe (71). Although, the underlying requirement for these pressures to be considered safe, was the ability of the individual to reposition themselves and relieve pressure during prolonged sitting.

1.1.3.2 - Shear forces

Shearing forces are caused when two opposing surfaces in contact, slide and cause a relative displacement. These forces are believed to cause angulation of blood vessels (72) and in turn occlude blood flow.

Studies performed by Bennett et al., show that externally applied pressure is twice as effective as shear force in blocking the flow of blood, however, they also contend that vascular occlusion is enhanced if both pressure and shear force is combined (73). These shearing forces may in fact cause many pressure ulcers (74) and are generally believed to be more injurious than simple point pressures, albeit concomitant to normal pressure.

One of the reasons why shear force is considered more damaging is its ability to cut off large areas of tissue from their vascular supply (64). Even raising the head of a hospital bed by a few inches is capable of producing shearing forces in sacral and coccygeal areas (15,72).

Shear force largely affects the subcutaneous tissue and is accentuated by the lack of tensile strength in this tissue (65). Thus, in a way, the quality and integrity of this tissue also plays a major role. Bennett et al, detected average shear force values developed by the geriatric hospitalized group were thrice those developed by young healthy subject group (75).

An important point to note here is that, most of the studies concerning shear forces and their effect of pressure sore development have concentrated on tangential (to the skin surface) forces. These are likely, the most common shear forces seen in daily activities of a majority of individuals. What is not known and studied is the effect of shear forces which are normal to the skin surface. These forces develop when an active cushion or a mattress is going through its

cycle of inflating and deflating cells; the boundary of inflation deflation can potentially result in shear forces.

1.1.3.3 - Friction

Dry friction may be encountered in the daily routine of a bed- or chair-bound individual. It is the force that resists relative motion between two surfaces in contact. Incontinent individuals may also experience lubricated friction. It has been shown that friction reduces the amount of pressure needed to produce ulcers (35). Friction can play multiple roles in lowering the quality of life experienced by bed- or chair-bound individual. It can enhance pressure ulceration, lead to dermal infections, and it may also complicate pressure ulcer evaluation/screening by covering the tissue surface with blisters and rashes. In order to understand the role of friction one must distinguish the different types of frictions an individual may encounter.

Dry friction is subdivided into static and kinetic friction. Static friction is the force that resists motion between two non-moving surfaces, and kinetic friction between moving surfaces. Static friction can be experienced by an individual during routine repositioning (using motorized wheelchair or done manually; *explained in section 1.2.2.1 - Self-Adjustment*), or while performing tasks. Kinetic friction is more common in a clinical setting, experienced when individuals are dragged across the bed sheets.

Static friction is the causative force for angulation of tissue: shear force. Kinetic friction can cause superficial ulcers, by eroding (65) or "fatiguing" the skin (76).

1.1.3.4 - Moisture

Perspiration, fecal or urinary soilage has been suggested to increase the risk of pressure sore formation five-fold (3,65). However, it is often difficult to ascertain whether such ulceration

should indeed be termed as pressure ulcer. Often continence related complication - incontinence dermatitis or incontinence-associated dermatitis, are confused with pressure ulcers.

The European Pressure Ulcer Advisory Panel (EPUAP) proposed that moisture lesions should be differentiated from pressure ulcers in the year 2005 (77), after it was felt that this lack of differentiation led to inappropriate management and also inflated the number of pressure ulcers (78).

Better skin management - as simple as keeping skin dry - may greatly help in reducing the risk for a pressure ulcer.

1.1.4 Risk Factors

It has been discussed throughout the early chapters in this thesis that prevention is extremely important in pressure sore management. To begin prevention, potential high risk individuals must be identified (*see section 1.2.1 Risk Assessment Tools*). The factors themselves must also be identified and their significance studied.

In addition to the above mentioned etiological factors, researchers in the past have investigated various potential risk factors through clinical studies (3,12,79,80). These include but are not limited to - prolonged immobilization, sensory deficit, circulatory disturbances, poor nutrition, fractures, smoking, being dependent on self-care and dry skin. Of the many identified risk factors, four most commonly discussed in the literature are described here.

1.1.4.1 - Prolonged Immobilization

Prolonged immobilization has been greatly discussed as a risk factor in pressure ulcer formation. Being bed or chair bound increases the possibility of one of the above etiological factors to affect

tissue characteristics and in turn cause ulceration. Prolonged immobilization must be avoided if possible even at the expense of slight discomfort (standing, walking etc). However, in most cases, it is sometimes impossible to prevent such long term immobilization.

There are many ways an individual can end up immobilized for long durations. These range from simple post-surgery status to debilitating diseases (arthritis etc.), neurological injuries (spinal cord injury etc.), or just extended stays in intensive care units. The incidence of pressure ulcers has been shown to be inversely related to the number of times an individual is able to reposition himself/herself (81). The study measured the number of nocturnal movements in geriatric population. Berlowitz et al found that being bed or chair-bound significantly increased the risk of pressure ulceration (12).

1.1.4.2 - Sensory Deficit

A healthy individual may unconsciously reposition himself/herself, when seated or lying on a flat surface, to avoid any pressure ulceration, and he/she will do so quite frequently. It is the sensation of pain resulting from prolonged pressure that stimulates the repositioning in most healthy individuals. Healthy individuals seated in a wheelchair were observed to perform a movement approximately every nine minutes in the sagittal plane and every six minutes in the frontal planes respectively (52). These movements prevent any pathological changes in the tissue and the act of performing the movements itself may increase perfusion due to tightening/relaxing of muscles.

In individuals with sensory deficits, like those with a spinal cord injury, the lack of sensation of pain impedes the ability to perceive any pain and the accompanying reaction. The additional

motor deficit that such individuals face further limits their motion and predisposes the individual to pressure ulcer formation (3).

1.1.4.3 - Circulatory Disturbances

It can be inferred that lower blood perfusion would increase tendency for pressure ulceration.

Both blood oxygenation and perfusion are important. Circulation helps remove waste matter (excretion), provide nutrients and oxygen to the tissue. Poor oxygenation, secondary to anemia, blood dyscrasias or other cardiovascular compromise may increase tendency for ulceration and also delay the process of healing (3).

1.1.4.4 - Poor Nutrition

Nutrition is especially important in cases where body has to perform repairs within or cope with disease state. Poor nutrition could hinder injury repair and may also decrease body fat and tissue quality. The subcutaneous fat provides the cushioning effect to both skin and muscle tissue and may decrease point pressures acting on both. Malnutrition leads to reduction in subcutaneous fat and also delays wound healing (3,82).

Many cross-sectional studies have shown a correlation between malnutrition and pressure ulcers (12,83-85). Malnutrition has also been associated with lower peripheral lymphocyte count and impaired cell immunity (85). There are readily available tests that can be performed on patients to measure lymphocyte count and serum albumin levels, which in turn could help assess the level of nutrition (85,86).

1.2 Prevention and Treatment of Pressure Sores

Pressure sores are, in most cases, preventable and every effort should be made to prevent them.

Although researchers are still working on understanding the exact cause and pathway of pressure

ulceration, many of the intrinsic and extrinsic factors have been highlighted. As has been discussed earlier, the most significant factor is surface pressure. Most strategies used in prevention are based on lowering the interface pressure and if not possible repositioning the individual to provide "pressure relief". Avoiding shear, friction and moisture is also important. At risk individuals should be regularly checked for any skin ulcers at least once a day, thoroughly checking bony prominences (87). Skin has to be kept well hydrated, free of excess moisture and clean (88). Using absorbed under pads or topical moisture barriers can be helpful (87). Friction and shear are commonly experienced when the subject is dragged off a bed or a wheelchair during a transfer. Lifting the individual and loosening the sheets to allow for movement would help avoid both shear and friction.

The intensity and extent of these prevention activities depends on the risk factor for pressure ulceration of an individual. Hence it is essential that the individual at risk is identified and appropriate prevention technique used.

1.2.1 Risk Assessment Tools

There have been many assessment tools developed to identify at-risk individuals, these include - Norton scale, Braden scale, Anderson instrument, the Vaperm Patient Support System, movement monitoring and thermography (15). Although most of these tools have not been thoroughly tested for their reliability and/or validity, they are all useful as an educational tool for the staff. The Agency for Health Care Policy and Research has recommended using either the Norton scale or the Braden scale to predict at-risk individuals (87).

Risk assessments tools should be applied to individuals who are bed or chair-bound or those who have very limited ability to reposition themselves. In general these tools use the known risk

factors and assign scores to each depending on how severe each factor is present in the individual. The score is then added up and a total score for an individual assigned. Depending on the specific scale, the scores vary and most usually have a threshold value, below or above which the individual is considered to be at risk.

It should be noted that these tools are subject to the personnel assigning the scores and the experience of the personnel here gains significance. Of all the scales Braden scale is reported to have a good inter-rater reliability. The Braden scale has six factors which include sensory perception, moisture, activity, mobility, nutrition, friction and shear. Each of the six factors is graded with a score of 1, 2, 3 or 4 (Factor 6 has a maximum possible score of 3); with a score of 4 representing lowest factor risk. Thus the best possible score would be 23. A total Braden scale score of 16 or less on the Braden scale indicates risk for development of pressure sores (15).

In the Norton scale, physical condition, mental condition, activity, mobility and incontinence are assessed. Each factor has a similar score scale as in Braden scale for a maximum possible score of 20. A total Norton scale score of 14 or below indicates risk (89).

Modern technology permits measuring the interface pressure at the interface of the supporting surface and the body tissue or clothing. These electronic pressure measuring devices paired with a computer data recording station are then used to assess the interface pressures of individuals sitting/laying down. Most contemporary systems visualize pressure data as a pressure map (usually color coded). It has been shown that using pressure maps has a higher reliability between inter-raters than using numerical data (90). Clinicians use the pressure sensing mats to determine if an individual shows higher pressure over the support surface used which in turn predicts an increased risk of pressure ulceration.

Once an individual is assessed to be at-risk for developing pressure sores, appropriate prevention techniques should be immediately applied. The present study considers individuals who are chair-bound and it is appropriate to look at various prevention methods used in this population group.

1.2.2 Pressure Sore Prevention Methods in the Wheelchair-bound

Unlike bedridden individuals, chair-bound individuals experience higher pressures owing to the smaller area supporting the majority body weight. It is recommended that the individual repositions themselves every 20-30 min (15). This can be done in a variety of ways - performing wheelchair push-ups, leaning forward/backward, using motorized wheelchairs that change the seating position (91,92). These approaches rely on the individual to voluntarily perform these tasks and require good physical and mental health. Some other techniques use a more involuntary method, usually using cushions/mattresses that automatically help relieve pressure.

1.2.2.1 - Self-Adjustment

A cost-effective and simple procedure to relieve pressure is to periodically perform repositioning maneuvers and/or exercises while sitting in a wheelchair. Movements as simple as leaning forward or backward, or rolling side to side can modify the interface pressure (93). A wheelchair push-up is an effective way to relieve pressure from most bony prominences in the seated posture. Individuals with low upper-extremity strength (geriatric population etc.) or those with quadraplegia cannot perform these exercises. Those that can perform these exercises have higher risk of injury or progression of shoulder pain (94). Performing these movements may cause painful muscle spasticity in some individuals (93).

Patients with sensory deficit may not realize the amount of time spent in one position and may fail to perform a pressure relief exercise. For such individuals, several monitoring systems are currently available. Devices as simple as a time logger, which provides an audio/visual signal to the individual indicating the need to perform a pressure relief exercise can be used. A more complex pressure monitoring device can do the same when a set threshold of either time, pressure or both, is reached (95-97).

Coggrave et al have suggested that these pressure relief maneuvers may be too short to allow proper reperfusion (98). Using ischial transcutaneous oxygen measurements, the mean duration of pressure relief required to raise tissue oxygen to unloaded levels was determined to be 1 min. 51 s. Even those individuals with the requisite upper body strength may be unable to maintain an elevated body position for such a long duration.

In such a situation, the use of motorized wheelchair that can tilt-in-space and recline may be beneficial. The Rehabilitation Engineering and Assistive Technology Society of North America recommends the use of Tilt and Recline wheelchairs for wheelchair users who are at risk for pressure ulcers (99).

Tilt-in-space involves the posterior rotation of the supporting wheelchair itself at the apex of the back and bottom support. The posterior movement of the back support in relation to the bottom support on the wheelchair constitutes recline. The possible combinations of tilt-in-space angles and Recline angles are many. Jan et al studied the effect of these angles using Laser Doppler Flowmetry (LDF). LDF measures the skin perfusion over the ischial tuberosity in response to the changing angles. They concluded that a recline of 100° (calculated from cushion base) combined with wheelchair tilt-in-space of 35° resulted in a significant increase in skin perfusion.

There are manual wheelchairs which allow for Tilt and Recline feature, but these require effort on part of the individual or a care-giver to perform these maneuvers. Motorized wheelchairs are better suited to perform larger angles of tilt-in-space and recline. These wheelchairs are expensive, owing to the additional electric motor and microprocessor usage.

For all the above approaches, the individual still has to choose to perform these maneuvers. A study performed by Stockton et al, on pressure relief behavior of wheelchair users indicated that many wheelchair users who were capable of performing pressure-relieving movements without help, either did not do them or did not adhere to current advice of relieving pressure frequently (100). Pressure relief mechanism should ideally be sustainable, efficient and not dependent on the individual's will or awareness.

1.2.2.2 - Support surface based

The advantage of using support surface based interventions for pressure relief is that these are not dependent on the user and as such, trivializes the issues involved with self-care. Many support systems are currently available for seating and beds. The support surfaces can be classified into two groups: static support surfaces and dynamic support surfaces. As the name suggests, static cushions/mattresses are reactive systems which do not impart or use energy. They react to the individual's body contour and weight. Dynamic cushions/mattresses presently available use air-filled chambers that inflate or deflate. The pattern of the inflation and deflation and the cycle-time between the inflation and deflation is not standard and has not been extensively tested.

Static Cushions

Pressure relieving static surfaces usually depend on the material used in construction of these surfaces and their design for pressure relief. An effective cushion design for wheelchair users should typically reduce interface pressure, provide comfort and promote good sitting posture. There are many different types of static cushions currently available in the commercial market. The four major types are: foam, visco-elastic foam, gel, and fluid floatation (15). Depending on the lifestyle of an individual, pressure sores risk, continence and cost, one of these four cushion types is usually chosen. Static surfaces are suitable for individuals who can periodically reposition themselves.

Foam is widely used as a support surface material. It is inexpensive, widely available and lightweight and can be quite easily modified suiting the needs of the individual. Foam cushions provide good postural stability. However, the material property of foam changes with usage and it wears readily. This makes it less than ideal for prolonged use.

Air-filled seating surfaces consist of air cells arranged in a grid that forms the supporting surface. These support surfaces are light weight and easy to clean. The air-filled cushions work by matching the individual's body contour, thereby increasing the surface area in contact and lowering interface pressure. They can be fit to a wide variety of individuals. The disadvantage of this system is that it is subject to punctures. In an event of air-loss the individual may end up sitting on a much harder surface and may have increased risk of pressure sores. Another major area of concern is user stability. Although, the Roho Quadtro cushion (ROHO Inc., Belleville, Illinois) addresses this issue by dividing the air cells in blocks (quadrants). By preventing air flow between quadrants, relative stability is achieved.

Liquid-filled seating surfaces use liquids/gel in a bladder as the supporting surface. The Jay J2 Recline Cushion (Sunrise Medical, Boulder, Colorado) cushion uses a hard base that holds gel-filled cells. The gel based cushions work similar to air-filled: they fit snugly to the contour of the user and increase the contact area. These have an added advantage of better user stability. The cushion themselves are heavy and can be tasking for manual wheelchair users. The problem of "bottoming out" can be prominent. Bottoming out is when the support surface under the subject loses its original properties due to a leak and/or movement of material in the bladder. Bottoming out generally results in users sitting on a harder, stiffer surface and as such may increase the interface pressure and risk of pressure sores.

Dynamic Cushions

Dynamic cushions/mattresses try to alter the interface pressure through periodically dropping air-chambers. This periodic pressure relief is considered beneficial (17,93,101,102). And as has been discussed earlier, the sole purpose of repeatedly off-loading the tissue is to promote good blood circulation and lower the risk of ulceration.

Unlike static cushions, which aim at lowering the maximum interface pressure, dynamic cushions are designed to deliver higher pressures to support the individuals in some locations to allow the deflating of cells and complete relief of pressure in other areas over short period of time. The inflated/deflated cells then alternate and continue to support the individuals, theoretically allowing for complete pressure relief in the currently deflated regions.

We believe the construction of dynamic cushions which consist of alternating air-pressure technology, should be based on four criteria - the pattern of inflation/deflation (or the design of

air-cell grid); the surface area/design of each cell that undergoes inflation/deflation; the cycle-time - the time period of inflation/deflation; and the air pressure in the inflated air cells.

Alternating therapy used in bed-bound individuals has a wider evidence base (15,103) while there are fewer studies relating to chair-users. The few that were carried out with chair-users do show promising results (93,104).

1.2.3 Treatment

Sometimes no amount of preventive measures can prevent an individual from developing pressure sores. Prevention guidelines should still be followed even after an individual develops pressure sores (91). The first step in treatment of a pressure sore is to relieve the pressure off the sore. Risk factors should be considered while starting a treatment plan designed for an individual, i.e., the management of ulcer should address the physical and mental condition of the individual. Local conservative therapy can help heal stage I, II and III ulcers. Stage IV ulcers, especially ones that have formed over the ischial tuberosities require surgical intervention (15).

Local wound care is essential, and it is important to keep the area clean and free from infection (91). Regular assessment of the ulcer should be carried out and documented using tracing or photographs (105). To keep the local wound bacterial count to a minimum, topical antibiotics can be used (3).

Mechanical debridement of all nonviable tissue contributes to accelerating wound closure (3,105). The presence of necrotic tissue hinders wound healing. The most effective and readily available treatment is sharp debridement using a scalper or scissor (105), and is recommended in the presence of advancing sepsis (15,105). If bacteria is detected in deep tissue cultures and the wound is not healing, further intervention is required, which may involve further debridement,

use of systemic antibiotics or a combination of both (105). Once all the scar tissue and infection is removed a moist wound-healing environment must be established (105). Such an environment is shown to promote reepithelialization, provides a barrier to bacteria, reduces pain and supports tissue repairs (106).

Skin care is important in the healing of pressure ulcers. In addition to skin care, maintaining good nutrition status can enhance the healing process (107). A complete nutritional status of the individual must be thoroughly evaluated, and a comprehensive diet regiment adopted. Blood tests and body-weight measurements may help in the assessment. Electrical stimulation, addition of exogenous growth factors and hyperbaric oxygenation may enhance pressure ulcer wound healing (15).

Full thickness pressure ulcers may warrant aggressive operative debridement. Such surgical interventions must be reserved for patients who do not show improvement with conservative methods. The method of reconstruction depends mainly on the size of affected tissue. In some cases, bone removal may even be needed.

1.3 Previous Cushion Evaluation Studies

Although there is a lack of consensus among various seat cushion researchers on what modality needs to be used to compare or even evaluate a cushion's performance, the most commonly used method is measuring the interface pressure between the seat and the seated subject. Despite its many limitations, interface pressure measurement is currently the only robust, easy to interpret and easily available technology that can potentially be used to evaluate the efficacy of the cushion in lowering the risk of pressure ulcers.

Interface pressure measurements indicate how a surface distributes the pressure developed by a user's body weight. Studies done previously have shown a correlation between higher interface pressure measurements and higher incidence of pressure ulcers (108,109). This high interface pressure threshold - over which the risk of acquiring pressure sores increases, has not been precisely identified yet. A generally accepted value for this threshold is 30 - 35 mmHg (*see Section 1.1.3.1*). However there are some studies which report a higher threshold level (110,111). One such study done by Conine et al found that the incidence of pressure ulcers was significantly higher among those patients who experienced peak pressures over 60 mmHg (109). Although there exists little agreement on this critical pressure, the general recommendation is to aim for the lowest possible interface pressures to lower risk of pressure ulcers (112).

Care must be taken when comparing different studies which use interface pressure measurements as the main outcome. The relatively low accuracy of pressure mapping systems and variability in devices used make it difficult to interpret and compare results (108). Relative measurements between different conditions using the same sensor system are recommended for comparing and evaluating support surfaces (108).

Studies similar to ours, have used interface pressure measurements to compare/evaluate cushions(113-118). There are many other studies that have used seat interface pressure measurements in the research fields related to wheelchairs and pressure sores (101,108,119-122).

Interface pressure is not the sole method that has been employed to evaluate and compare cushions. Tissue deformation capacity was used as a predictor of cushion performance in a study done by Levine et al. (123) Seat contour analysis (124),thermal properties of the cushion (125) and blood perfusion measurements (108) have also been used.

1.4 Overview of Masters Work

This study was carried out in collaboration with Kansas Neurological Institute (KNI), Topeka, KS. The choices made in the development of protocol and execution of this study were influenced by the clinical experience of the occupational therapist, Ken Lassman, OT, at KNI. The wheelchair seat cushions used in this study were fabricated by ROHO Group Inc., at their manufacturing plant based in Belleville, Illinois. The cushion design was based on the connection patterns jointly developed by ROHO and us.

1.4.1 Research Objectives

The focus of my thesis work was to investigate the effect of cushion design (pattern of inflation/deflation of a dynamic cushion) and cycle-time (time span of inflation/deflation) on the pressure relieving characteristics of an alternating air-pressure active seat cushion (dynamic cushion). The dynamic cushions were also tested against a static cushion, to verify any benefits associated with dynamic cushions.

1.4.2 Cushion Design Rationale

Based on our discussions with Ken Lassman, OT, KNI, we selected the cushions made by ROHO. ROHO designs and manufactures air-filled static cushions which are widely used in high-risk wheelchair users. "Quadro" cushions form the higher end of ROHO's products line up and have consistently lower interface pressures compared to other static cushions available in the market.

Alternating air-pressure mattresses for the bedridden are widely available and accepted as a prevention method against pressure ulceration. Most of these mattresses have a matrix of air cells that are grouped in a pattern that inflates and deflates alternatively. Some of the most common

patterns seen are the checkerboard pattern (where the connected individual cells are alternated) and column/row pattern (where a row or column of cells is grouped). Similar designs are also seen in a few dynamic cushions manufactured for wheelchair users, but none have been independently tested for efficacy or efficiency of the design.

In working with ROHO we found a partner who could fabricate such patterns and incorporate them into their leading cushion version (Quadro High Profile). As was discussed earlier, the problem of stability is inherent with any air-filled cushion. Quadro circumnavigates this problem by dividing the cushion into four independent quadrants (hence the name, Quadro) which prevent air flow from one section of the cushion to another. Incorporating the full four quadrant design in the dynamic version of the cushion would require an 8-channel air controller with a complicated set of connections between cells.

In order to provide stability and still provide alternating pressure relief, it was decided to divide the dynamic cushion into two sections. The front half, Section 1, where the subject would rest his thighs, and the back half, Section 2, where the subject would place his buttocks. Section 1 was again divided into two independent passive quadrants that were still static. Section 2, which would support the bony prominences, was designed to have an alternating pressure pattern.

The two patterns selected were Checkerboard, where connected cells were alternated as checkerboard pattern and Column, where the cells were divided into columns, running along the length of the thighs, and alternate columns were connected. For each design two groups of cells would then inflate and deflate alternately. The time of inflation and deflation, referred as cycle-time, were set to 6min. (3.5min. inflation, 2.5min. deflation) and 12min. (6.5min. inflation, 5.5min. deflation). These were chosen based on general recommendation of performing relief

measures periodically. Deflation time was less, to allow for co-inflation of both groups between deflations. A third cushion was also used as a control. This cushion chosen was a standard Quadro high profile static cushion.

1.4.3 Interface Pressure Mapping

As discussed earlier, interface pressure mapping has been widely used in comparing and evaluating seat cushions. We believe interface pressure measurements can yield parameters that can potentially be used to evaluate the performance of a dynamic cushion more objectively.

These parameters include the commonly used - peak pressures, mean pressure. We also looked at percent contact area under a threshold pressure over a cumulative time span of 5min. and percentage of active sensors under three different pressure thresholds.

The main outcome of the current study is interface pressure, as monitored using an interface pressure monitoring mat. Pressure below 30 mmHg was considered as a threshold value and is also referred to as "relief pressure" in this study. Cushions with larger area of pressure below this threshold were considered better.

1.4.4 Hypotheses

We hypothesized that using a dynamic cushion would provide significant pressure relief over a static cushion. We further hypothesized that the inflation/deflation pattern and cycle time would significantly influence pressure relief.

Specifically we hypothesized -

H1 - Dynamic cushion will have a larger cumulative area of pressure relieved (pressure below threshold of 30 mmHg) when compared to static cushion

H2 - Longer cycle-time would have a lower mean pressure and higher cumulative area of pressure relieved compared to shorter cycle-time.

H3 - The checkerboard pattern of inflation and deflation would provide better pressure relief than the column pattern.

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Chapter 2 Active Seat Cushion: Evaluating the effect of alternating-pressure pattern and cycle time on pressure relieving characteristics using interface pressure measurement

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2.1 Abstract

Objective: To examine the effect of pattern of inflation/deflation and cycle time on pressure relieving characteristic of active cushions; to compare the performance of these active cushions with a standard passive cushion.

Design: Repeated measures experimental study.

Setting: University laboratory.

Participants: Convenience sample of 10 non-disabled individuals.

Intervention: Interface pressure was measured for 24 minutes using Xsensor pressure mapping system.

Main Outcome Measures: Peak and mean pressures, percent surface contact area under 30 mmHg for a cumulative time of at least 5 minutes and mean percentage of activated sensors under three thresholds (20, 30 and 40 mmHg).

Results: The column cushion (COL) had significantly ($p<0.05$) lower mean pressures compared to both the checkerboard cushion (CHK) and the passive cushion (PAS). COL also had significantly higher ($p<0.05$) percent of surface area relieved compared to both CHK and PAS, while CHK was also significantly better than PAS. Both COL and CHK had higher mean percent of sensors showing pressure under 20 mmHg, while only COL had higher percent values for pressure under 30 mmHg. No significant differences were observed in mean percent of sensors under pressure 40 mmHg. Significantly higher peak pressures were observed during 12 min.

cycle time compared to 6 min. cycle time, while there were no significant peak pressure differences between the three cushions.

Conclusions: Active cushions have an advantage over passive cushions for interface pressure. Design parameters of active cushions can significantly influence the pressure relieving characteristics of the cushion. A column pattern appears to have better performance than a checkerboard pattern.

Keywords: Pressure ulcers; wheelchairs; rehabilitation; Technology, medical

2.2 Introduction

Intermittent pressure relief has been recommended as a means to lower the risk of Pressure Ulcer (PU) development (1). Prolonged application of pressure over skin surface is one of the most significant factors, and in most cases the only requisite factor, that may result in the development of Pus (1,2). Thus, using an active seat cushion (i.e., a cushion that cyclically changes the area of exposure to pressure) seems like a logical method in helping lower the risk of PU formation in the chair-bound population.

Seat cushions can be broadly classified into two groups – static cushions (passive cushions) and dynamic cushions (active cushions). Static cushions depend on the material used in their construction and their design to help lower seat interface pressures. These typically include foam, air and gel-based cushions. Static cushions aim at evenly distributing pressures and thus lowering the peak pressures at the interface between the individual and the seat surface. Static cushions do not completely relieve pressure. An active cushion, on the other hand, may increase interface pressure at some portions of the surface in contact, while providing complete pressure relief to the remainder. In successive alternating cycles, the high pressure points are then

relieved. Ideally, active cushions should relieve all of the contact area for enough duration so as to allow periodic reperfusion of the tissues to normal levels.

Coggrave et al (3) measured the duration of pressure relief required to raise tissue oxygen level to unloaded values using ischial transcutaneous oxygen measurements in Spinal Cord Injured (SCI) individuals. They found this required duration to be as high as 3 min. 30 s (1 min. 51 s mean). The traditional pressure relief maneuver of lifting up the body from the seat, as performed by individuals who have the requisite upper body strength and control, only allows a few seconds of reperfusion. In addition to this it is recommended that the individual performs such relief maneuvers several times each hour (4-6). Sustaining and repeating these exercises for longer durations may be impractical and, in some cases, also detrimental to the individual's upper extremities.

There are a wide variety of active cushions in use today. Most use air pressure to inflate groups of air cells arranged in the cushion while letting some of the other cells to passively deflate. This process is then alternated and the deflated cells are inflated while the inflated cells are deflated. The time period between two successive inflations of an air cell is called cycle time. Cushions differ in the structure and arrangement of these air cells and the cycle time.

Some of the common arrangement of air cells include rows or columns of air cells shaped as cylinders where alternate rows inflate and deflate (e.g. Blue Chip's Chair-air cushions), air cells arranged in a grid with box like cells inflating and deflating in different patterns - rows, columns or checkerboard (e.g. Talley's B.A.S.E cushions) and custom shaped cells specifically designed for each contour of the seated individual that alternatively inflate or deflate (e.g. Aquila's Airpulse PK cushions).

The rationale behind the use of such active cushion designs has not been well researched. There is surprisingly little information available on the effect of any design parameter on the pressure relieving characteristics of one active cushion compared to another. One of the difficulties in making an objective evaluation of such parameters is the lack of suitable technology and standardized cushion designs. Interface pressure (IP) measurement, though it has limitations, has been widely used to compare the pressure characteristics of cushions. High IP values have been shown to correlate well with PU development (7).

Active cushions require dynamic IP measurements since pressure relief in them is time dependent. Rithalia et al (8-11) have in the past used dynamic IP measures to compare active mattresses. They looked at parameters such as duration of pressure under three thresholds, in addition to conventional IP data such as peak pressures and mean pressures.

The objective in this preliminary study was to determine the effect of inflation pattern and cycle time of inflation and deflation on the pressure relieving characteristics of active cushions. We also compared active cushions with a static cushion as a control.

2.3 Methods

2.3.1 Study Design and Sample

A repeated measures randomized design was used to test the differences between two experimental cushions and one standard cushion. Approval for the study was obtained from the Human Subjects Committee at University of Kansas. Ten non-disabled subjects (2 female, 8 male, weight 73.8 ± 15.9 kg, age 22.9 ± 2.6 years) were recruited for this study and gave signed consents.

2.3.2 Cushion Design

The standard cushion in our study was a commercially available static Quadtro High Profile (The Roho Group Inc., Belleville, IL) air cushion. The advantage of using a Quadtro cushion was its ability to fit a wide range of individuals without the need for major modifications. This cushion is divided into four quadrants that can be isolated using a valve at the front. The valve allows or prevents airflow between quadrants and provides good user stability when locked.

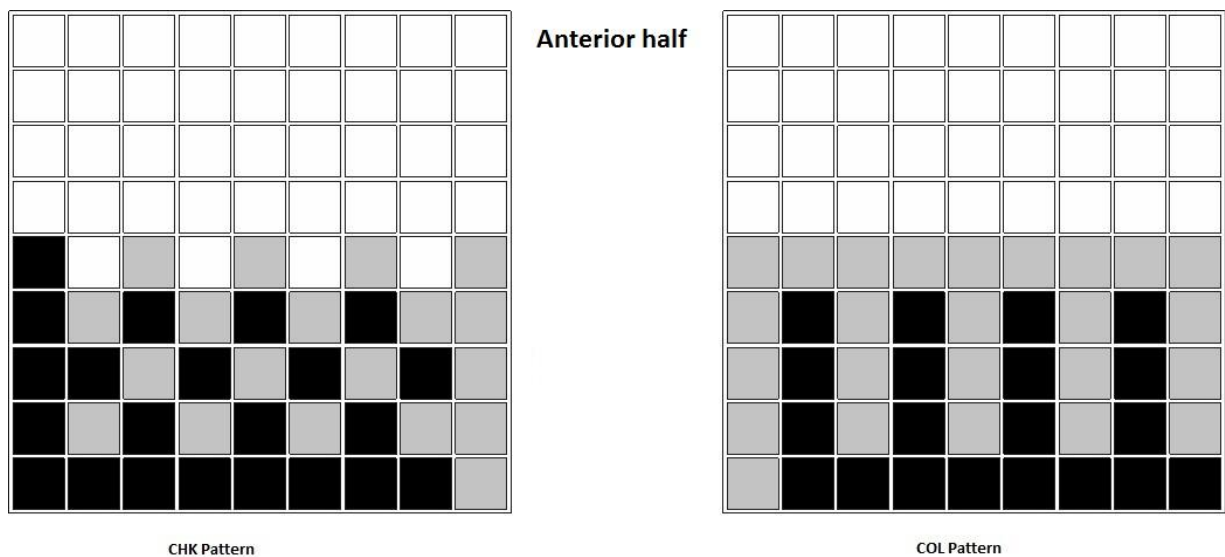


Figure 2.1 Illustration of the active cushion designs used in this study. White color represents passive cell. Grey and black show the two patterns of inflation-deflation.

The other two cushions were active cushions based on the Quadtro design and had modified air cell connections (Figure 2.1 and Figure 2.2). In order to avoid possible instability, these cushions were divided into two halves. The front half consisted of two standard static Quadtro High Profile quadrants, while the back half was the active alternating part. The anterior half could be isolated from the back half using the valve in the front. The two patterns of connections were checkerboard pattern and column pattern. In the checkerboard pattern, cells located on the same color of an imaginary checkerboard placed on the cushion, were grouped into two separately inflated sections and connected to two air channels from the control box. Column pattern

consisted of connecting adjacent cells of a column running parallel to sides of the cushion. Alternate columns were then grouped and the two groups were individually connected to the control box. The control box controlled the periodic inflations and deflations of the two groups. This control box was connected to a modified Aero-Pulse alternating pressure air pump, which provided air flow for pressurization.

The control box could be adjusted to different cycle times. These cycle times were selected to be 6 minutes and 12 minutes. Each full cycle consisted of one group of cells undergoing one complete inflation and deflation. A 6 min. cycle time consisted of 2.5 min. of deflation with overlap (dual inflation) for 0.5 min. between deflations of each channel. The 12 min. cycle time had 5.5 min. of deflation and 0.5 min. of overlap.



Figure 2.2 Picture of a standard ROHO Quadro High Profile air cushion. Both the active cushions were identical to this cushion in all aspects including cell size, structure and layout.

The standard Quadro cushion (PAS, for passive), checkerboard pattern active cushion with 6 min. cycle time (CHK6) and 12 min. cycle time (CHK12) as well as the column pattern cushion, COL6 and COL12, were experimentally compared.

2.3.3 Pressure Measurements

The Xsensor model X3 (Xsensor Technology Corporation, Calgary, Canada) was used to measure seating interface pressure in this study. The sensor was calibrated in the range 10-200 mmHg. Each individual transducer element had a sensing area of 1.6 cm². The sampling frequency was set at 2 Hz, and data was collected and stored on a computer. The accompanying Xsensor software, X3 Medical V6, was used to acquire, display and export data.

2.3.4 Experimental Procedure

Subjects were advised to wear soft clothing. Every subject was seated in each of the cushions tested in a random order. A standard wheelchair was used for all the tests, with foot rest height adjusted for different leg lengths. The seat of the cushion was parallel to the ground and the back rest at 90°. Each subject was positioned with their elbows resting on the arm-rests and feet on foot rests, and with hips, knees and ankles flexed at 90°.

Cushions were enclosed in a manufacturer recommended seat cover. After seating the subject over the sensor mat covering the cushion, the Xsensor system was run under *Preview* mode while the cushion was inflated or deflated until lowest possible mean and peak pressures were observed and the pressure distribution was approximately homogeneous.

The passive half of the cushion was always adjusted as described above. For the active systems, subject's buttocks were positioned on the active half of the cushion (with the Xsensor sensing mat). Data collection was started after one complete unrecorded cycle in active systems and after 5 min. of stable sitting on the passive cushion. Data was collected for 30 min. Data was continuously visually inspected and the subjects were monitored. Trials with noticeable motions were excluded and repeated.

2.3.5 Data Collection

Data was displayed in the Xsensor Medical V6 software and regions of interest were selected.

The software allows for grouping of sensors using basic drawing tools. For active systems, a rectangular selection including the entire active region was analyzed. For the passive cushion, a rectangular which mimicked the active region selection and which included the Ischial Tuberosities and coccyx was analyzed (Figure 2.3). Then, 24 min. of data from the beginning of data collection was exported for each test. This provided two cycles for the 12 min. cycle time and four cycles for the 6 min. cycle time, as well as 24 min. of passive cushion data.

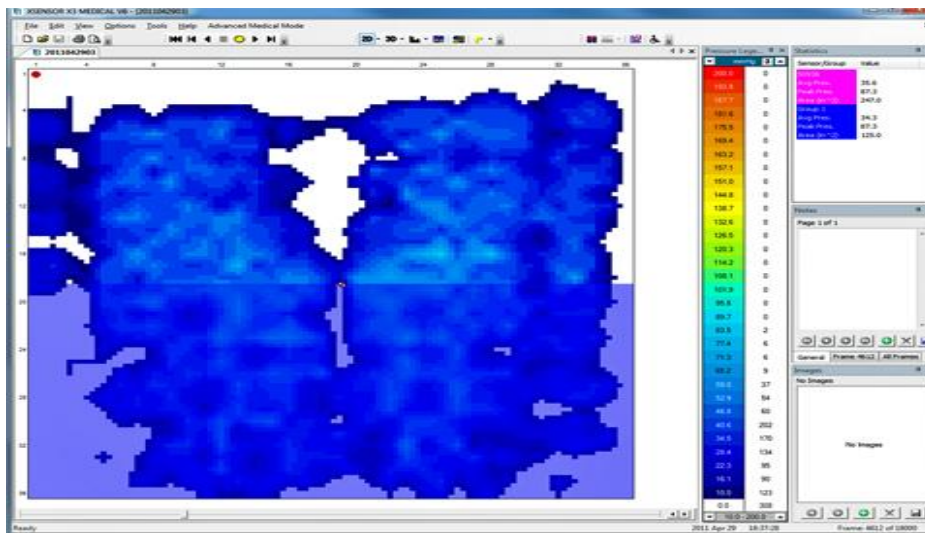


Figure 2.3 The shaded rectangular section is the selected region of interest for this particular data set. This was done using the group sensors tool in Xsensor Medical V6.

The pressure distribution data was then analyzed using custom code written in Matlab (The MathWorks, Natick, MA, USA). Before quantitative analysis, the data was pre-processed to eliminate non-loaded sensors. Xsensor assigns sensors below the calibrated threshold of 10 mmHg to be 0 mmHg. Using a threshold technique, zero data for sensors which were non-zero for at least 50% of total test time were re-assigned as the mean of the lower threshold and zero (5 mmHg) and all other zero valued sensors ignored for further analysis.

2.3.6 Variables Analyzed

We calculated variables which we believed would provide important comparisons between cushions. These variables were somewhat based on prior work (12). We calculated the peak (p_{max}) and mean (p_{mean}) seating interface pressures. The maximum pressure has been considered a useful output parameter and is most commonly reported (13,14). However in comparing active seating systems, maximum pressure may not hold much significance since pressure is alternated.

Based on approx. 30 mmHg capillary closing pressure we also calculated the mean of percentage of sensors below three thresholds: 20, 30 and 40 mmHg, labeled $P<20$, $P<30$ and $P<40$, respectively.

To account for temporal differences in pressure, we calculated the percentage of contact area under 30 mmHg for at least a cumulative duration of 5 min. during data collection (labeled $S>5$) and time averaged peak pressures (time avg. P_{max}), which included the mean of all sensors which reached within 5% of absolute peak pressure value at least once during the entire 24 min. of data analyzed.

2.3.7 Statistical Analysis

All data were tested for normal distributions. 2-way repeated measures Analysis of Variance (ANOVA) was done on data from the active systems to test for significance of effects and interactions between pattern and cycle time. A 1-way *repeated measures* ANOVA was run to compare the differences between absolute peak pressure and time averaged peak pressure for each cushion. A subsequent 1-way *independent* ANOVA was run comparing the three patterns (PAS, CHK and COL) using pooled cycle time data for active cushions. When the ANOVA

indicated significant differences, a Bonferroni post hoc analysis was performed. A probability $p < 0.05$ was considered significant for all comparisons. Statistical analysis was performed in PASW Statistics 18 (IBM Corporation, Somers, NY, USA).

2.4 Results

Results of the 2-way repeated measures ANOVA showed significantly better performance ($p < 0.05$) of the column (COL) cushion pattern compared to checkerboard (CHK) in percent surface area in contact with pressure under 30 mmHg for at least 5 min. ($S > 5$), mean percentage of sensors under two thresholds ($P < 20$, $P < 30$) (Figure 2.4) and overall mean pressure (Figure 2.5). Peak pressures were not affected by the cushion type, but significantly higher peak pressures ($p < 0.05$) were observed during the 12 min. cycle time compared to the 6 min. cycle time.

In order to compare the active cushions to the standard passive cushion (PAS) a subsequent 1-way independent ANOVA was run with pooled active cushion data. The results of this analysis showed both the active systems (CHK and COL) performed better compared to PAS. Significant differences ($P < 0.05$) were observed between all three cushions for $S > 5$ with COL best and PAS worst. With increasing threshold value, there were decreasing significant differences between areas under the threshold for PAS and CHK, while differences between PAS and COL continued to be significant (Figure 2.6). As expected, there were no significant differences between the three cushions when the peak pressures were measured. However, COL has significantly lower mean pressures compared to both CHK and PAS. (Figure 2.7) Though active cushions performed better than passive results also indicated elevated time averaged edge pressures at the junction between air cells in active cushions (Figure 2.8).

The results of 1-way repeated measures ANOVA indicated significant difference between peak pressures and their corresponding time averaged peak pressures for all three cushion types (Figure 2.9). Although no significant differences were observed between cushions for time averaged peak pressures, active cushions had larger differences between peak pressure values and corresponding time average of pressure for those points at peak pressure. A plot of pressure variation in sensors which reached the absolute peak pressure value in a typical active cushion showed cyclic low and high pressure values while minimal pressure variation was seen in the passive cushion (Figure 2.10).

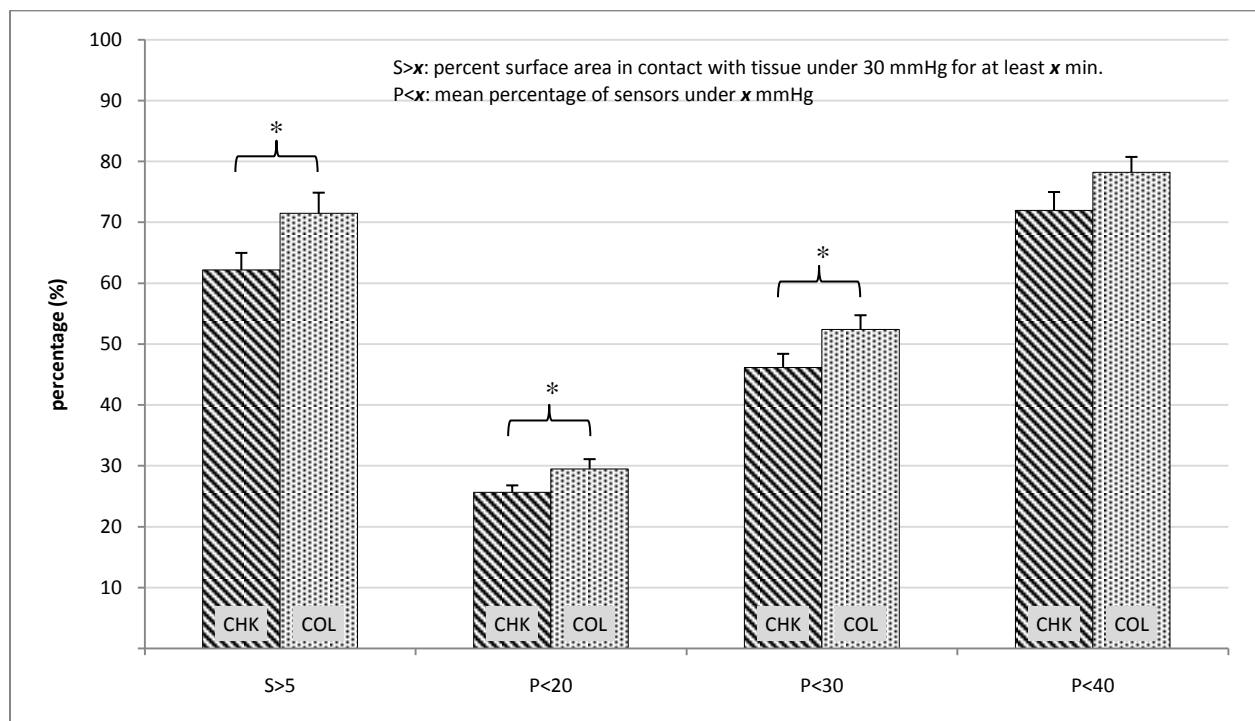


Figure 2.4 Results of 2-way repeated measures ANOVA for cushion type indicated the column cushion (COL) provides lower pressures for more time and over larger surface area than the checkerboard cushion (CHK). Error bars represent standard error. Significance ($p<0.05$) denoted by *.

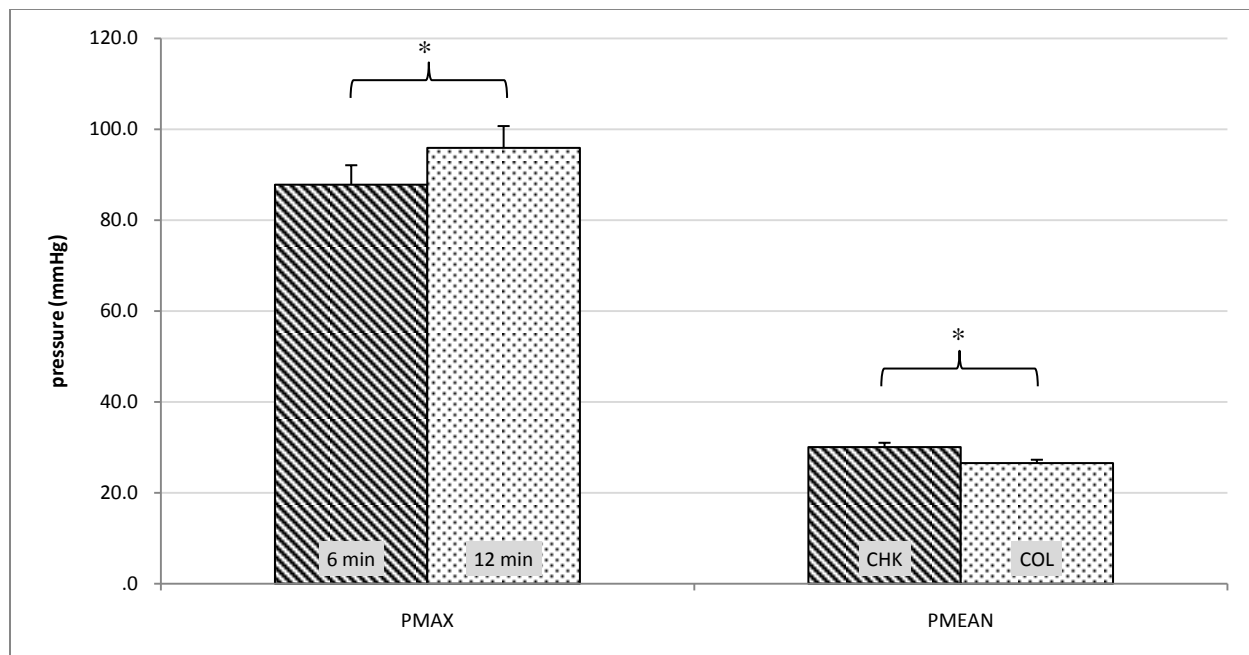


Figure 2.5 Results of the 2-way repeated measures ANOVA indicated significantly higher peak pressures during the 12 min. cycle compared to the 6 min. cycle. Significantly lower mean pressures in COL compared to CHK were also observed. Error bars represent standard error. Significance ($p < 0.05$) denoted by *.

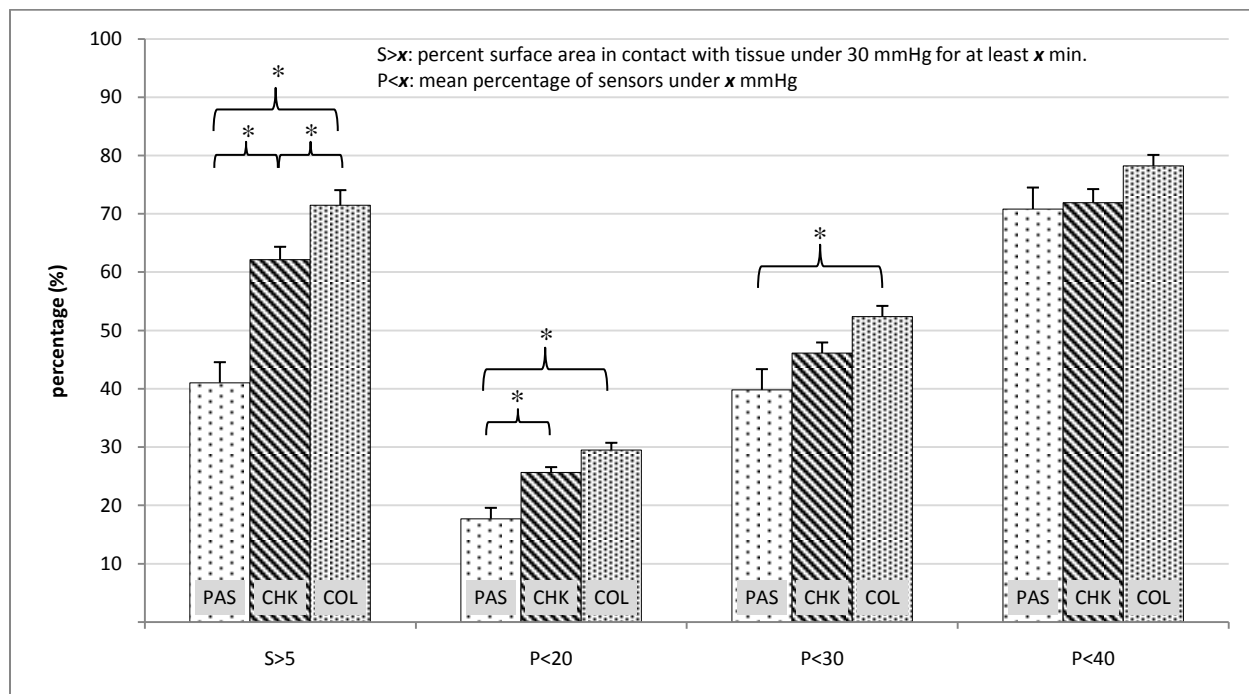


Figure 2.6 Results of the 1-way independent ANOVA for cushion type indicated that COL provided better pressure relief characteristics compared to CHK and passive cushion (PAS). Also, CHK was better compared to PAS. Error bars represent standard error. Significance ($p < 0.05$) denoted by *.

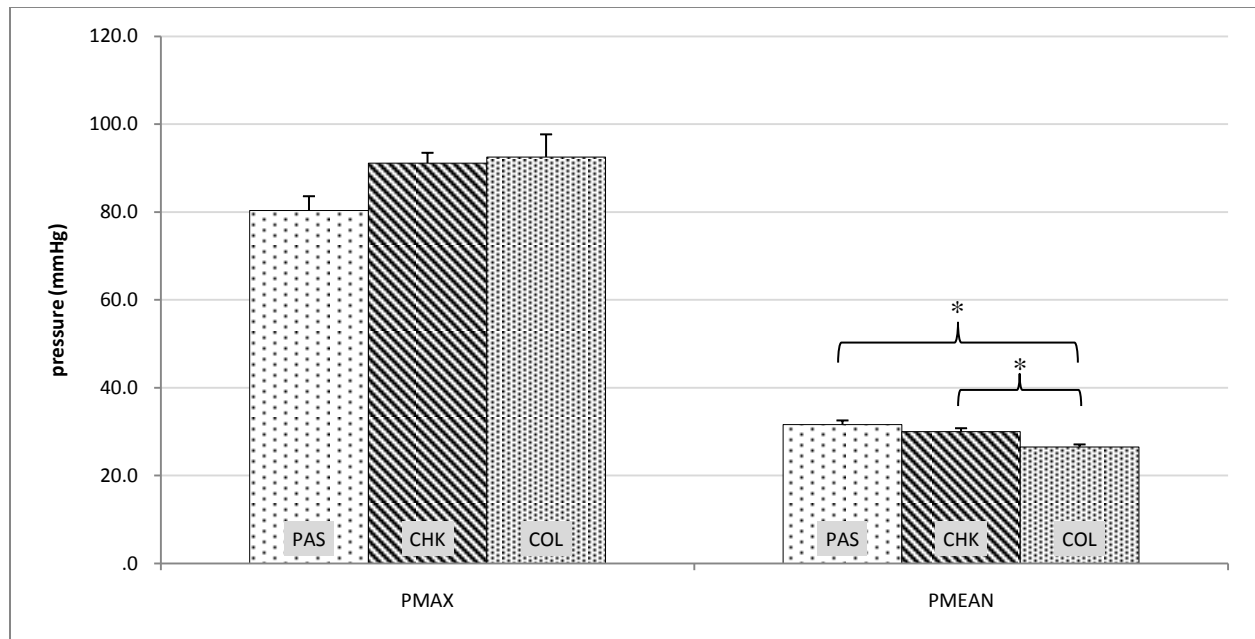


Figure 2.7 Results of the 1-way independent ANOVA indicated COL had significantly lower mean pressures compared to both PAS and CHK. A trend of higher peak pressures in active cushions compared to PAS was observed. (as would be expected). Error bars represent standard error. Significance ($p < 0.05$) denoted by *.

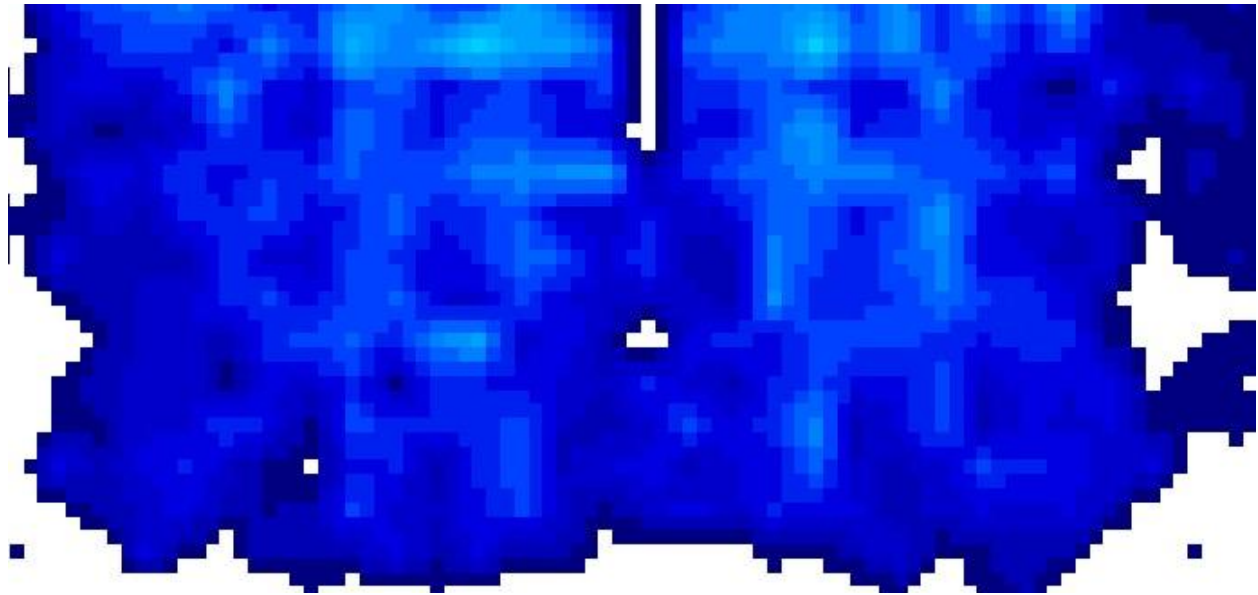


Figure 2.8 Screen capture showing the average pressure distribution in the active part of CHK. Lighter shades indicate higher pressures.

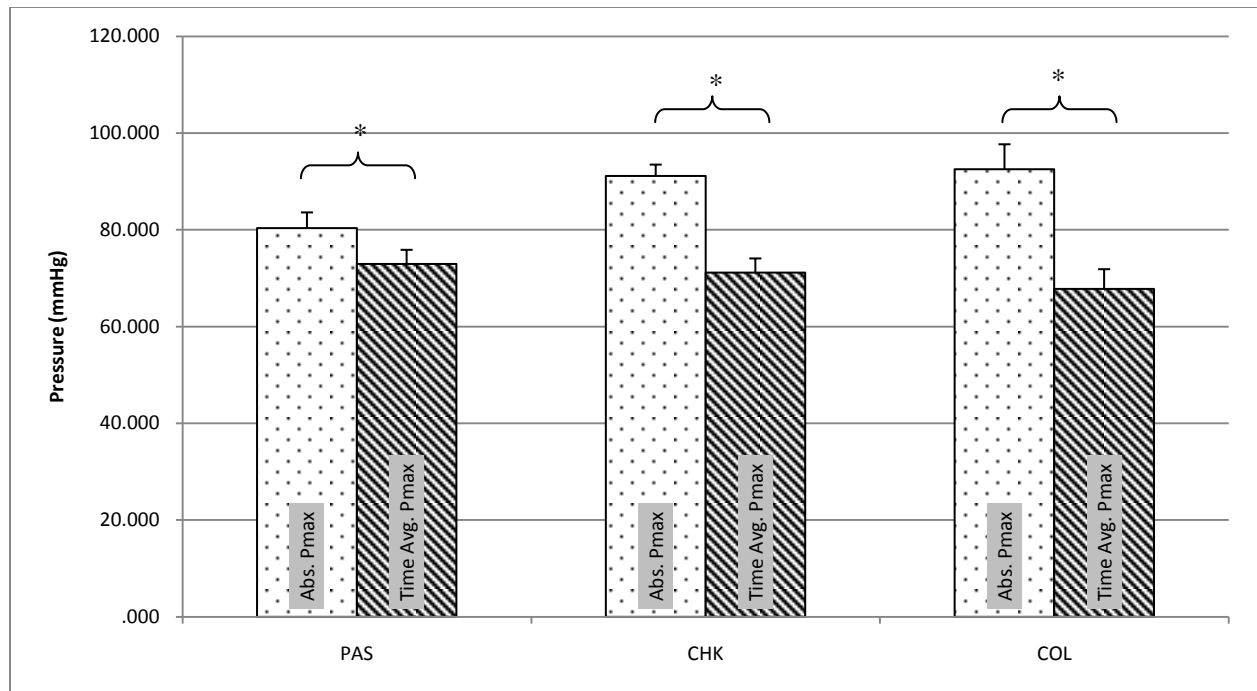


Figure 2.9 Results of 1-way *repeated measures* ANOVA for difference between absolute peak pressures and time averaged peak pressures. Error bars represent standard error. Significance ($p<0.05$) denoted by *.

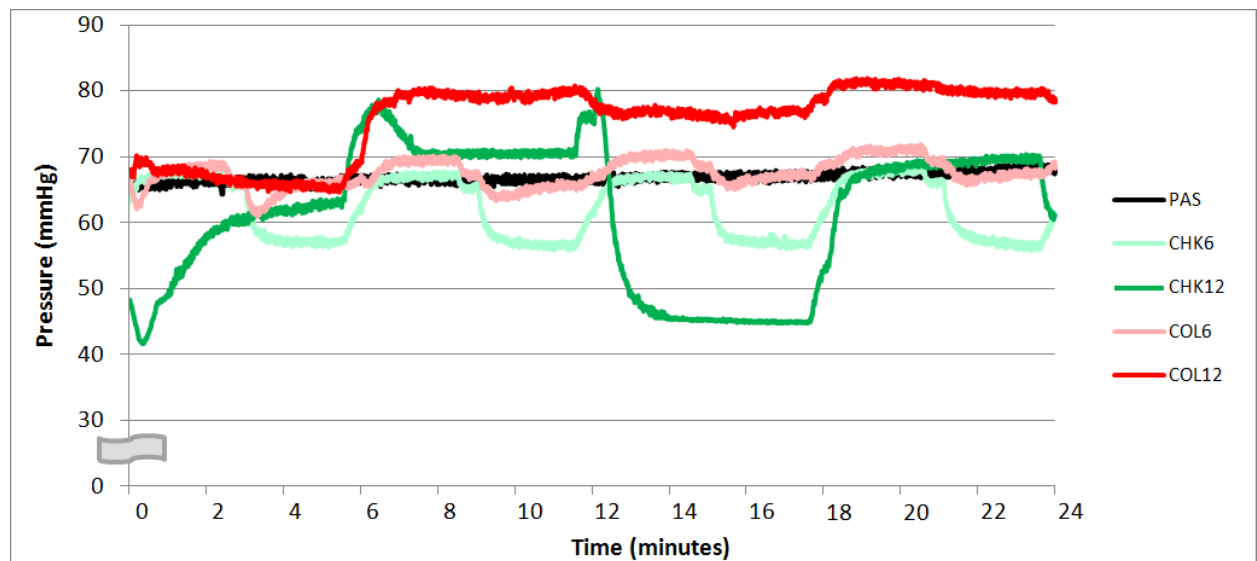


Figure 2.10 Line graph showing the pressure variation of sensors which reached each respective cushions absolute peak pressure value during 24 min. of data collection.

2.5 Discussion

In this study, we developed custom active cushions that were designed to compare the effect of pattern of inflation and deflation and cycle time on the pressure relieving characteristics of the

cushion. Based on the sample of cushions analyzed in this study, the active seating system with column based pattern of inflation and deflation (COL) exhibited the best mechanical performance with regards to the parameters calculated.

The pattern of alternating pressure is an important parameter and has many repercussions. We found COL performed better than both checkerboard (CHK) and passive cushion (PAS). However, these results may have been heavily influenced by the cushion design and construction. The circuitous pathways in CHK appear to have resulted in slower deflation and inflation. Also, COL had more cells deflating directly inside the body contour compared to CHK. The air distribution pathways may also explain the significant differences in peak pressures observed between the two cycle times. Longer cycle time would allow longer time for the cells to inflate more, creating higher interface pressures. It can be inferred that cycle time is design dependent, and it may be inappropriate to generalize cycle times based on one or two cushion designs.

The peak pressure points in all the cushions had significantly lower time averaged pressures, however this difference was quite large in both the active cushions, considering both had higher peak pressures compared to the passive cushion. As was seen in the plot showing the variation of these peak pressure points, both the active cushions did have intermittent pressure relief even at these high pressure points while the passive cushion had nearly constant high pressure, which further supports the use of active cushions.

One of the problems with an active seating system is user stability. The act of deflation - inflation may cause the feeling of instability in the user. Keeping the contact area nearly constant during the alternation, could help keep the user stable. Another method to increase user stability

would be to mimic the isolated sections of a Quadtro cushion. However, this would require additional connections and complicate the control system used. The weight of subject can also affect the pressure relieving characteristics of an active cushion. Heavier subjects may need cushions with larger air cells and high internal air pressure to support their body weight while comparatively smaller cells and lower internal air pressures may suffice a leaner individual.

PU's can occur at any location with unrelieved pressure; however, it is more common near bony prominences. In a seated individual, regions adjoining the sacrum, coccyx and ischial tuberosities are usually affected by PU's (15,16). Some active systems have been designed to predominantly relieve these bony prominences. This design seems logical, since major risk areas are being relieved. However, there is little information available on whether these designs do provide optimal pressure relief. This custom design does have a few disadvantages. Each cushion has to be custom fit to suit the individual's contours. The individual also has to be positioned correctly to take advantage of this design. In a situation such as this, using a generic design where a group of similarly sized and shaped cells alternate the surface pressure may be beneficial; however, the degree of pressure relief achieved may still be dependent on the location of tissue and cushion design (recall lower relief on edges of cells). Using a generic system would allow to use the system with a wide range of individuals.

Active cushions may help lower the risk of PU development but should not be used as the only prevention strategy. Lack of any movement can have a detrimental effects on the individual (17). Repositioning may be difficult when using active cushions, based on the custom design since these depend on the precise seating of the individual. The act of repositioning may end up moving the individual from the required position needed for optimal pressure relief.

One of the problems possible with most active cushions is the generation of shear forces. Shear has been shown to reduce the pressure needed to create a PU to nearly half (18). The alternating edges in an active cushion may cause shear normal to the surface of the skin. It is currently unknown if active cushions could promote deep tissue injury or surface PUs due to shear forces. Also, higher edge pressures noted by the time averaged pressure distribution show possible limitations of active cushions. These edge pressures may be due to the close spacing of cells. Inflated cells may expand into adjacent spaces, occluding pressure relief at the edges. Tissue overlying the edges of cells may have lower reperfusion and may become focal points of PU development. This illustrates the need for carefully designing improved active cushions.

Limitations

This study was a pilot study designed to test for feasibility and to develop protocol for a clinical trial. Our study was limited by the small study size (N=10) and testing of non-disabled individuals. The cushion designs were based on existing passive Roho Quadtro cushions. The air connections between the cells in a Quadtro are designed to prevent rapid movement of air. These connections hindered faster air-flow that appears to be needed in the active cushion. The connections designed to create the checkerboard and column pattern may also have produced some differences in the data, as CHK has more complicated and lengthy connections. Finally, the internal air pressure of the cushions was not varied to accommodate the subject's body weight. Still this study provides valuable insight that can be used in dynamic cushion design.

2.6 Conclusions

We investigated the effect of pattern of alternation of pressure and cycle time in active cushions. Active cushions had advantages over passive, and the column pattern performed better than checkerboard. A redesign of cushions to allow for better air flow and a full scale trial with

disabled persons is needed to fully understand the importance of pattern, cycle time and air cell size.

2.7 Acknowledgements

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Chapter 3 Additional Discussion and Future Recommendations

In this study, I developed and tested custom active cushion systems that were designed to compare the effect of pattern of inflation and deflation and cycle time on the pressure relieving characteristics of the cushion. I also tested a standard passive Roho Quadro cushion (PAS) as a benchmark. Based on the sample of cushions analyzed in this study, the active seating system with anterior-posterior column pattern of inflation and deflation exhibited the best mechanical performance with regards to the seat pressure parameters calculated.

Cushion design is an important factor and based on our experience in this study, I believe there are six major design parameters that significantly influence the pressure relieving characteristics of an active seat cushion. These six parameters are: pattern of inflation and deflation, air-distribution pathways, air cell structure, air cell size, internal air pressure of the air cells and cycle time of inflation and deflation.

Active cushions strive to provide complete pressure relief to, ideally, the entire tissue surface in contact with the cushion. In order to do so, without compromising user stability, the pattern of inflation and deflation should provide a balanced contact area. The pattern of inflation and deflation was limited in this study by the use of a 2-channel air flow controller, as more complex patterns would require complicated control hardware and software. In this study, column pattern (COL) performed better than the checkerboard pattern (CHK). However, cushion design may have influenced these results. The present active cushion systems used the passive Quadro air-distribution pathways. The pathways have high air resistance, which is needed in passive cushions for stability. These resistive pathways combined with the circuitous pathway in CHK appear to have resulted in slower inflation and deflation. COL also had more cells deflating

directly inside the body contour in contact compared to CHK. Another aspect to consider is the effective cell size; COL had effectively larger contiguous deflating air cell area. Developing designs which have better connection patterns to create a CHK or similar inflation/deflation patterns may provide better objective comparisons.

Another observation made in this study was the presence of higher average edge stresses on the boundaries of air cells undergoing inflation/deflation. These edge stresses could develop shear normal to the surface of the skin. Also, the tissue overlying the edges of the cells may have lower reperfusion and may become focal points for pressure ulceration.

Higher peak pressures are expected in active cushions and were also observed in this study. Temporal analysis of the sensors which had peak pressure reading revealed intermittent pressure relief in both the active cushions. Passive cushion on the other hand, had nearly constant pressure over the peak pressure sensor for the entire duration of data analyzed. This explains the significantly lower time averaged pressure over peak pressure points compared to absolute peak pressure, seen in both the active cushions, but does not explain similar significant difference observed in passive cushion. However if the magnitude of the difference is considered, it was quite low in passive cushion compared to both the active cushions.

We did not vary the air-cell structure in this study. Both the active cushions had the same standard Quadro high profile air-cell design. Pressure relief in an active cushion depends on the collapsing of air cells. A design which allows for efficient and complete collapse may be more effective compared to one in which even a deflated air cell has the structural rigidity to apply pressure to the body. The air cells in Quadro high profile are slender and have star shaped crux. This prevents an inward collapse of the cell, thus, even a deflated cell could possibly sustain an

unwanted residual pressure (though small). In case of active cushion the cell structure and shape need to be optimized for efficient inflation, deflation and pressure relief.

As was discussed above, stress concentration over the edges of inflating/deflating air cells must be lowered or avoided. Cell spacing may have a significant influence on these edge pressures. Cells too close to each other on inflation may expand into the adjacent deflating air cell space. This would prevent any pressure relief over this region. By increasing the gap between two air cells higher cell boundary pressures may be reduced. However, too large of a gap can also have a negative influence. Large air cell gap may induce the inflating air cells to inflate "side-ways" which can potentially drop the subject over the deflated air cells, depriving tissue off any pressure relief. The size of the air cells can significantly influence the edge pressures. A larger air cell, may provide pressure relief to larger surface area in contact at a time, and also have smaller contact area present over the edges, but it may generate larger magnitude of pressure on both the present edges and the inflated cells. The use of different air-cell sizes in the same cushion may be a solution. This design could be similar to the Enhancer Cushion by ROHO. The enhancer cushions uses air cells to help better position an individual, thus providing better lateral stability and enhanced midline channeling of the femurs. A region of larger air cells with lower height compared to surrounding cells could be used under the ischial tuberosities.

Internal air pressure of the air cells is important. However the internal air-pressure of an active cushion that allows for maximum pressure relief depends on a number of factors. These factors include the subject's body weight and the air-cell's size and structure. Testing a larger study group, with a wide range of body-weights could be helpful in determining an optimal internal pressure for a particular cushion design. In our study, the active cushion inflation pressure was constant regardless of the subject.

Cycle time controls the duration of high pressure and pressure relief in an active cushion.

Determining optimal cycle time for an active cushion is quite challenging. Active systems have been in use for more than half a century and yet there is no consensus on cycle times needed for optimal pressure relief. Cycle time depends on many factors and hence it is difficult to objectively test for an optimal value. Longer cycle times may expose tissue to higher prolonged pressures, while very short cycle time may not be sufficient for tissue to reach normal reperfusion levels. Testing with instruments that can read blood perfusion may help in identifying better cycle times, but it would require a large scale study with sufficient statistical power, and even with such a study designed, it may not be sufficient to generalize the results to a wider population group. There could exist a cycle time or at least a range of cycle times that can provide optimal pressure relief. This would require testing individuals divided into groups based on tissue quality and other factors, with different cycle times.

Future work should include re-designing and fabricating active cushions, followed by large scale testing of these cushions with non-disabled healthy individuals and if possible, disabled individuals. Basic research involving non-disabled individuals can answer a number of the design questions. Blood perfusion is another measurement that can be effectively used to analyze and compare active cushions. This should be included in future studies along with seat interface pressure measurement system.

Internal shear patterns with active cushions are difficult to predict with present testing technology. Until suitable technology is available, finite element modeling of the buttocks could provide some insights to the internal strain and stress patterns. However dynamic modeling of buttock and active cushion interactions may require development of complex models and extensive numerical simulations. Another approach would be to use medical imaging

technology. Magnetic resonance imaging or ultrasound can potentially provide tissue deformation information, which could be used to study the influence of dynamic motion on internal tissue properties. An ultrasound probe can potentially be combined with force measuring sensors to correlate force applied to tissue deformation.

The interface pressure measuring mat used in this study may not be suitable for a full scale trial to test the efficacy of designs of active cushions. Higher resolution sensors that can be attached to the subject at each high risk region of body in contact (e.g. ischial tuberosities etc.) may help more accurately measure pressure relief characteristics at these critical locations.

In summary, we investigated the effect of pattern of inflation and deflation and cycle time in active cushions. Active cushions had advantage over passive, and the column pattern performed better than checkerboard. We believe there exists tremendous potential in using active cushions for pressure ulcer prevention; however, a lot of work needs to be done in order to understand the design parameters that go into making an effective cushion before it can be used to replace present passive pressure relieving cushions. The next step in this research project is to redesign the cushions to allow for better air flow and carry out a full scale trial, results of which may help us understand the importance of pattern, cycle time and air cell size.